K003335

NOV 17 2000

510(k) Summary September 27, 2000

Applicant:

Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, PA 19040
Reg. No: 2510954

Contact Person:

James G. Carpenter
Ph: (215) 675-5200
Fx: (215) 682-8689

Device trade/proprietary name:

Resuscitaire® Radiant Warmer
Resuscitaire® Birthing Room Warmer
Resuscitaire® Wall Mounted Radiant Warmer

Device common/usual/classification name:

WARMER, INFANT RADIANT

Classification:

General Hospital
21 CFR 880.5130
Infant Radiant Warmer, FMT, Class II

Performance Standards:

None applicable.

Predicate (Current) Device:

K940951 RW Resuscitaire Infant Radiant Warmer

Device Description

The Resuscitaire® Radiant Warmer is designed specifically for labor and delivery room use. The Resuscitaire® Radiant Warmer consists of a Bassinet, Warmer, and controller module, which provides heat control, monitoring of skin temperature and Apgar timing. The Resuscitaire® Radiant Warmer also includes an optional basic resuscitation package, which includes suction and oxygen delivery.

Intended Use:

The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, Apgar timing, and resuscitation of newborn infants.

This is the same intended use as previously cleared for the RW Resuscitaire® Infant Radiant Warmer, K940951 RW Resuscitaire Infant Radiant Warmer.

Description of Modifications:

The modifications that are the subject of this submission are summarized below:

- Addition of a new resuscitation module using the existing module with the following changes.
  - Change the 15mm outlet on the Gas Delivery Module to a tapered, barbed fitting that is consistent with currently accepted caregiver practice in the United States and Canada.
  - Replacement of the user adjustable airway relief valve with an internal fixed relief valve.
  - Appropriate modifications to module overlay and user manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2000

Mr. Larry W. Krasley
Regulatory Affairs Specialist
Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, Pennsylvania 19040

Re: K003335
Trade Name: Resuscitaire Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: October 24, 2000
Received: October 25, 2000

Dear Mr. Krasley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Resuscitaire Radiant Warmer

Indications for Use:

The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, Apgar timing, and resuscitation of newborn infants.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

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(Optional Format 1/2/96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003335